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Application Number		10575905
Filing Date		2007-04-30
First Named Inventor	Hatto	ri et al.
Art Unit		1644
Examiner Name	llia I.	Ouspenski
Attorney Docket Numb	or or	14875-01611181

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	1	1510943 E		EP		2005-03-02	SAITO et al.			
	2	1870459	EP			2007-12-26	IGAWA et al.			
	3	09506001	JP			1997-06-17	LINDHOFER et al.			

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	4	9533844	wo		1995-12-14	LINDHOFER et al.				
	5	9627011	wo		1996-09-06	CARTER et al.				
	6	9803546	wo		1998-01-29	BOONE et al.				
	7	2006106905	wo		2006-10-12	IGAWA et al.				
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	1	FISH & RICHARDS No. 10/575,193, file			y to Action date	d September 24, 2009 in U.	S. App. Ser.			
	2	U.S. EXAMINER MICHEL EDWARD SZPERKA, USPTO Final Office Action in U.S. App. Ser. No. 10/575,193, mailed June 23, 2010, 18 pages								
	3		luman Physiology	, R.F. Schmi	idt, G. Thews (E	and English translation: SC ds.), Second, Completely R g, 1989		×		
	4	pancreatic juice," H	SCHMIDT et al., Human Physiology, Moscow, 3:764 (1996), and English translation: SCHMIDT et al., "Enzymes of the pancreatic juice," Human Physiology, R.F. Schmidt, G. Thews (Eds.), Second, Completely Revised Edition, 716 translated by Marguerite A. Biederman-Thorsonj, Springer-Verlag, 1989							
	5	ADAMS et al., "Hur inhibitor, pertuzuma				ody to produce a therapeutic 7 (2006)	HER dimerization			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

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 14875-0161US1

6	BINZ et al., "Engineering novel binding proteins from nonimmunoglobulin domains," Nat. Biotechnol., 23:1257-68 (2005)	
7	BRANDEN and TOOZE, "Recognition of Foreign Molecules by the Immune System," Introduction to Protein Structure, 2d Ed., Garland Publishing, pp. 299-323 (1999)	
8	COMPER and GLASGOW, "Charge selectivity in kidney ultrafiltration," Kidney Int., 47:1242-51 (1995)	
9	CCUTC et al., "Anti-BA46 Monoclonal Antibody Mc3: Humanization Using a Novel Positional Consensus and In Vivo and In Vitro Characterization," Cancer Res., 55:1717-22 (1995)	
10	DEEN et al., "Structural determinants of glomerular permeability," Am. J. Physiol. Renal. Physiol., 281:F579-F596 (2001)	
11	DEL RIO et al., "An Engineered Penicillin Acylase with Altered Surface Charge Is More Stable in Alkaline pH," Ann. NY Acad. Sci., 799:61-64 (1996)	
12	DILLON et al., "Structural and functional characterization of disulfide isoforms of the human IgG2 subclass," J. Biol. Chem., 283:16206-15 (2008)	
13	EWERT et al., "Stability improvement of antibodies for extracellular and intracellular applications: CDR grafting to stable frameworks and structure-based framework engineering," Methods, 34:184-199 (2004)	
14	GHETIE and WARD, "FcRn: the MHC class I-related receptor that is more than an IgG transporter," Immunol. Today, 18:592-598 (1997)	
15	GHETIE et al., "Increasing the serum persistence of an IgG fragment by random mutagenesis," Nat. Biotechnol., 15:637-640 (1997)	
16	GHETIE et al., "Multiple roles for the major histocompatibility complex class I- related receptor FcRn," Annu. Rev.	

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17	GOBBURU et al., "Pharmacokinetics/dynamics of 5c8, a monoclonal antibody to CD154 (CD40 ligand) suppression of an immune response in monkeys," J. Pharmacol. Exp. Ther., 286.925-930 (1998)	
18	GOODE et al., "The glomerular basement membrane charge-selectivity barrier: an oversimplified concept?," Nephrol. Dial. Transplant., 11:1714-16 (1996)	
19	GRAVES et al., "Molecular modeling and preclinical evaluation of the humanized NR-LU-13 antibody," Clin. Cancer Res., 5:899-908 (1999)	
20	GUPTA et al., "Affinity chromatography and co-chromatography of bispecific monoclonal antibody immunoconjugates," J. Biochem. Biophys. Methods, 51:203-216 (2002)	
21	HANSON et al., "Catalytic antibodies and their applications," Curr. Opin. Biotechnol., 16:631-636 (2005)	
22	HE et al., "Humanization and pharmacokinetics of a monoclonal antibody with specificity for both E- and P-selectin," J. Immunol., 160:1029-35 (1998)	
23	HINTON et al., "An engineered human IgG1 antibody with longer serum half-life," J. Immunol., 176:346-356 (2006)	
24	ITO et al., "The His-probe method: effects of histidine residues introduced into the complementarity-determining regions of antibodies on antigen-antibody interactions at different pH values," FEBS Lett., 309:85-88 (1992)	
25	KASHMIRI et al., "Generation, characterization, and in vivo studies of humanized anticarcinoma antibody CC49," Hybridoma, 14:461-473 (1995)	
26	KHAWLI et al., "Improved tumor localization and radioimaging with chemically modified monoclonal antibodies," Cancer Biother. Radiopharm., 11:203-215 (1996)	
27	KIM et al., "Antibody Engineering for the Development of Therapeutic Antibodies," Mol. Cells, 20:17-29 (2005)	

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28	KIM et al., "Chemical modification to reduce renal uptake of disulfide-bonded variable region fragment of anti-lac monoclonal antibody labeled with 99mTc," Bioconjugate Chem., 10:447-453 (1999)	
29	KIM et al., "Lowering of pl by acytation improves the renal uptake of 99mTc-labeled anti-Tac dsFv: effect of different acytating reagents," Nucl. Med. Biol., 29:795-801 (2002)	
30	KOBAYASHI et al., "The pharmacokinetic characteristics of glycolated humanized anti-Tac Fabs are determined by their isoelectric points," Cancer Res., 59:422-430 (1999)	
31	KREUTZ et al., "Efficient bispecific monoclonal antibody purification using gradient thiophilic affinity chromatography," J. Chromatogr. B, 714:161-170 (1998)	
32	LINDHOFER et al., "Preferential Species-Restricted Heavy/Light Chain Pairing in Rat/Mouse Quadromas," J. Immunol., 155:219-225 (1995)	
33	LOBO et al., "Antibody pharmacokinetics and pharmacodynamics," J. Pharm. Sci., 93:2645-68 (2004)	
34	MANZKE et al., "Single-step purification of bispecific monocional antibodies for immunotherapeutic use by hydrophobic interaction chromatography," J. Immunol. Methods, 208:65-73 (1997)	
35	MARTIN et al., "Crystal structure at 2.8 A of an FcRn/heterodimeric Fc complex: mechanism of pH-dependent binding," Mol. Cell, 7:867-877 (2001)	
36	MARVIN et al., "Recombinant approaches to IgG-like bispecific antibodies," Acta. Pharmacol. Sin., 26:649-658 (2005)	
37	MARVIN et al., "Redesigning an antibody fragment for faster association with its antigen," Biochemistry, 42:7077-83 (2003)	
38	MERCHANT et al., "An efficient route to human bispecific IgG," Nat. Biotechnol., 16.677-681 (1998)	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

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39	ONDA et al., "Lowering the Isoelectric Point of the Fv Portion of Recombinant Immunotoxins Leads to Decreased Nonspecific Animal Toxicity without Affecting Antitumor Activity," Cancer Res., 61:5070-77 (2001)	
40	PAVLINKOVA et al., "Charge-modified single chain antibody constructs of monoclonal antibody CC49: Generation, characterization, pharmacokinetics, and biodistribution analysis," Nucl. Med. Biol., 26:27-34 (1999)	
41	PAVLOU et al., "The therapeutic antibodies market to 2008," Eur. J. Pharm. Biopharm., 59:389-396 (2005)	
42	PODUSLO et al., "Polyamine modification increases the permeability of proteins at the blood – nerve and blood-brain barriers," J. Neurochem., 66:1599-1609 (1996)	
43	RAJPAL et al., A general method for greatly improving the affinity of antibodies by using combinatorial libraries," Proc. Natl. Acad. Sci. USA, 102:8466-71 (2005)	
44	RATHANASWAMI et al., "Demonstration of an in vivo generated sub-picomolar affinity fully human monoclonal antibody to interleukin-8," Biochem. Biophys. Res. Commun., 334:1004-13 (2005)	
45	REICHERT et al., "Monoclonal antibody successes in the clinic," Nat. Biotechnol., 23:1073-78 (2005)	
46	SAL-MAN et al., "Arginine mutations within a transmembrane domain of Tar, an Escherichia coli asparlate receptor, can drive homodimer dissociation and heterodimer association in vivo," Blochem. J., 385:29-36 (2005)	
47	SCHAEFFER et al., "The Rat Glomerular Filtration Barrier Does Not Show Negative Charge Selectivity," Microcirculation, 9:329-342 (2002)	
48	SEGAL et al., "Bispecific antibodies in cancer therapy," Curr. Opin. Immunol., 11:558-562 (1999)	
49	SHAUL, "Exploring the charge space of protein-protein association: a proteomic study," Proteins, 60:341-352 (2005)	

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	SHIELDS et al., "High resolution mapping of the binding site on human IgG1 for Fc gamma RI, Fc gamma RII, Fc gamma RII, Fc gamma RIII, and FcRn and design of IgG1 variants with improved binding to the Fc gamma R," J. Biol. Chem., 276.6591-6604 (2001)						
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